REMARKS

The amended Claims submitted herewith are believed to address the indefiniteness rejections set forth in the outstanding Office Action (Page 2, paragraphs 1 – 5).

With added regard to Claims 1 – 11, such have been amended to better clarify one of the key points of the present invention and one that distinguishes such from the patent to Kee—that is, that the present Russo invention specifically defines an open unobstructed lumen configuration which, as will be more fully discussed, is clearly absent in Lee. While it is recognized that the word "open" may include a little bit open like Lee, that is not the type "open" that Russo has clearly defined in the current application. That type of "open" lumen in the Russo invention is one in which you could drive a train through—no boulders, no stalled railcars and no vestiges of other operational equipment in this tunnel—but a "straight through" completely "open unobstructed" tunnel. Applicant has amended these Claims (1 – 11) so that it is clear that the above described "open" is the open that is set out in the Claims and an open that clearly distinguishes from the open of Lee in which operational equipment almost totally blocks the lumen passage and which can cause the problems indicated on Page 4 of the subject Specification.

The Examiner has rejected Claims 1,2,4-8, and 10 as being anticipated by Kee U.S. Patent No. 6,070,582. The Kee suction control valve patent '582 is simply a more complicated but still deficient version of the suction control valves of

Palmer (U.S. Patent Nos. 4,569,344 and 4,696,296) discussed at great length in the present application. The Kee '582 device suffers from all the same and additional deficiencies of the Palmer valves. Both Palmer and Kee valves have the same type of valve core **40** (Kee FIG. 3), conical valve seat **35** conical bore **32**, elastomeric spring **30**, and most importantly valve flow channel **41** notched out of core **40**. Both Palmer and Kee have virtually identical structures and function in the same exact manner whether in their non-suction applied mode or their suction applied mode.

Both the Palmer and Kee valve types are static seal type valves in that they both have a central core member and a conical surface which is upwardly biased to seal against a conical valve seat located within the body of the valve. (see present Application Page 3, second paragraph) Both the U.S. District Court for the District of Utah and the United States Court of Appeals for the Federal Circuit in Case No. 00-1393 dated October 26, 2002 (Ballard Medical Products vs. Allegiance Healthcare Corp.) confirmed that the Palmer/Kee type suction control valves are static seal types as prior art discussed in the present application.

The Kee valve core partially blocks, that is, partially obstructs, the fluid flow path through the valve when the valve is actuated in its suction applied mode. (see present Application Page 3, first paragraph) By comparison, the present invention, as depicted in **FIG. 3** and described on page 10, second paragraph, has a slideable plunger **15** and piston **19** which moves downward upon manual depression

of actuator **17** such that cross lumen **20** will align itself with the central passageway and thus fully and completely open up central passageway **13** permitting unobstructed and unrestrictive fluid and air flow to take place through central passageway **13**. This is not how Kee functions. The Kee valve core **40** partially blocks fluid flow channel **36** and **39** when the Kee valve is actuated to its suction applied mode. Fluid and air flow is obstructed because valve flow channel **41** located as part of valve core **40** is nothing more than a notched out corner side channel of core **40**. This is clearly depicted in **FIG. 7** and **8** of Kee.

There is no open lumen as alleged by the Examiner in Kee when the valve is actuated in its suction applied mode at least not in the sense of a reasonable interpretation of the term "open". Thus since valve core **40** is present in and at least to a practically significant extent blocks fluid flow channels **36** and **39** when the valve is depressed to its suction applied mode in Kee. Thus, viscous secretions will build up in the Kee valve. This is not the case with the present invention (see Application Page 10 third paragraph, and Page 11 third paragraph). The Kee valve has a distorted tortuous disruptive flow path which is described in the present invention (see Application Page 11, third paragraph). In essence, the Kee valve structure has all the deficiencies and limitations as outlined in the present invention as part of the prior art suction control valves. Kee teaches the direct opposite of the High Efficiency Suction Control Valve of the present invention.

All of this can be easily visualized by the attached figures taken from both the present invention (**FIG. 3**) and compared to the Kee invention (**FIGS. 7, 8 and 11**). Both Kee and the present invention have been color highlighted.

Present Invention: **FIG. 3** is a side cross sectional view of the High Efficiency Suction Control Valve showing the valve positioned in its fully open suction applied mode wherein the plunger **16** and piston **19** are highlighted in blue. Most importantly a solid orange highlighted rod clearly shows how the valve's transversing passageway **13** is fully and completely open straight through valve cross lumen **20** such that no portion of plunger **16** or piston **19** obstructs fluid or air flow through the valve **10**.

Kee '582 Invention: **FIGs 7 and 8** are cross sectional views of the valve core of the fluid flow valving device showing the valve core **40** highlighted in blue and the small side notched out fluid flow channel **41** highlighted in yellow. **FIG. 11** is a cross sectional view of the fluid flow valving device showing the valve in the actuated position wherein the valve core **40** is again highlighted in blue. The fluid flow channel **41** is again highlighted in yellow and a solid orange highlighted rod clearly shows how fluid flow channel **36** is substantially blocked and obstructed by valve core **40** when the valve is actuated.

These color-highlighted figures give a clear visualization of the differences in the two valves and the superiority of the present invention High Efficiency Valve.

Further, the Examiner has completely missed the fact that the valve of Kee is specifically designed to permit the entrance of atmospheric air to pass through the valve to create an audible "hiss" when the valve is actuated. Kee describes air entering the valve through cap opening **21** (see **FIGs 2, 3**). Kee's valve structure completely contraindicates its use as part of a closed tracheal suction system since atmospheric air is intentionally designed to enter through the valve and on into the catheter and in turn subject the patient to airborne pathogens. As such, it should be noted that no where in all of Kee does he teach or allege that the Kee valve can be used as part of a closed tracheal suction system. Thus, one would not be led to combine Kee with Iund or Iund with Kee.

In direct contrast, the High Efficiency Suction Control Valve of the present invention is ideally part of a closed tracheal suction system (see abstract) in that the valve is specifically designed to be hermetically sealed from atmosphere (see page 9) which is the direct opposite teaching of the Kee suction control valve. Seal ring **18** completely seals off the interior of the valve from atmosphere. It should also be noted that the valve of Kee is very complex and has nine parts including a button **20**, valve core **40**, body **13**, upper cup **17**, lower cup **14**, spring **30**, bushing **47**, core

plug **46**, and compression spring **58**, compared to only three parts of the present invention.

As such, **claim 1** should be allowed since it has the limitation that the piston portion is positioned across said first passageway to hermetically seal off fluid and air flow. Secondly, it requires open, unobstructed and straight through fluid and air flow in its suction applied mode, which is not the case with Kee. Dependent **Claims 2,4,5,6,7** should also be allowed. **Claim 3** should be allowed since **FIG. 4** and page 12, second paragraph describe and show wiper seal "O" ring **26** integrally molded as part of plunger **16**. **Claim 8** should also be allowed since it has the limitations of being hermetically sealed and unobstructed fluid and air communication. Dependent **Claims 9-11** should also be allowed.

As to Iund et al '840, the Iund tracheal suctioning device suffers from all the same deficiencies plus some others as outlined in detail on page 4 of the present application. Specifically, the Iund device does nothing to remove viscous secretions which will accumulate in the manifold assembly and be reintroduced to cause VAP (ventilator associated pneumonia). The Iund device is completely different in structure when compared to the present invention and therefore has none of the features, benefits, and advantages of the present invention. The present invention (See **FIGs 6-9**) clearly discloses, describes, and depicts a totally hermetically sealed airtight closed tracheal suctioning system.

Compared to the present invention, the Iund device:

1. Does not have a catheter cleaning chamber adjacent to the manifold assembly having both a catheter wiper and an isolator seal

2. Does not have a catheter isolator tunnel behind the catheter cleaning chamber.

3. Leaves the catheter in the ventilator air stream (see **FIG. 4**) which will reintroduce secretions back into the patient's airway.

4. Requires a catheter introducer tip **20** (**FIG. 4**) to open up barrier **155** unlike the present invention which opens up the isolator seal solely by the manual contact of the suction catheter with the isolator seal.

5. Does not have a funnel shaped catheter cleaning chamber having a catheter irrigation flush port designed to provide a vortex swirling cleaning action on the catheter.

6. Has a duck-bill type barrier which will grossly accumulate secretions surrounding the leafs of the duck-bill valve with no teaching or method to remove those accumulated secretions.

7. Only has a bronchial lavage port **130** (**FIG. 1**) which only dumps fluid into endotracheal port **140**. There is absolutely no mention or teaching of how a catheter can be cleaned. Iund is completely silent on any description or teaching of catheter cleaning. Lavage port **130** cannot possibly be used for catheter cleaning since it spills all its lavage solution into apertures **157 and 125**.

8. Does not teach an isolator seal which is 100% normally sealed airtight since it requires an additional cap **145** to seal off barrier **155**.

9. Permits secretions to collect on and around the catheter introducer tip **200** when the catheter is retracted with no teaching of how those secretions will be removed or cleaned which will lead to VAP because these secretions will remain within and around catheter nozzle **265** and catheter flange **260**, and

10. Permits secretions collected and remaining around both the barrier, catheter introducer tip, catheter nozzle and flange to be reintroduced into the patient's airway when ventilation is delivered through ventilation port **135**.

Many of the above distinguishing features can be visualized by the attached **FIG. 4** from Iund which has been color highlighted to show how secretions, highlighted in green, will accumulate around the barrier, catheter introducer tip, and catheter nozzle and flange. Administered ventilation is shown with orange arrows through ventilation port **135**. As the catheter is reintroduced, ventilation will pick up those secretions and deliver them back into the patient through endotracheal port **140** as outlined in the present invention.

It is clear then that independent **Claims 12 and 34** which describe the cleaning chamber have language which is a clear distinction over Iund '840. Iund does not have a catheter cleaning chamber adjacent to a frontal manifold with the catheter cleaning chamber having both a catheter wiper and an isolator seal wherein the catheter wiper is positioned in front of the isolator seal, which are the

requirements of **Claims 12** and **34** of the present invention. As such, **Claims 12 and 34** and all their dependent Claims should be allowed.

Further, the Examiner asserts that Iund teaches a cleaning chamber. This absolutely is not apparent in any portion of the Iund patent that the Examiner can refer to in any language or figure. In fact, the area surrounding the barrier **155** cannot possibly be conceived of or used as a cleaning chamber since it actually is a breeding chamber for catheter retracted back secretions as readily illustrated by the attached highlighted **FIG. 4** from Iund. To build on this error to assert that the particular purpose, shape, and design of the cleaning chamber of the present invention can easily be substituted as a mere "design choice" to the Iund device is without foundation. In the present invention **FIGs. 7** and especially **FIGs 8 and 9** along with a detailed description of the advantages of the funnel shaped cleaning chamber described in minute detail on **Pages 14, 15 and 16** the manner in which the present invention clearly distinguishes over Iund or any other prior art devices. Last paragraph of **Page 15** of the present invention further outlines how the cleaning chamber **36** has been conceived and is specifically designed for the purpose of removing "the most viscous secretions such that no secretions will remain within the cleaning chamber after catheter cleaning which will significantly prevent their reintroduction when the catheter **44** is advanced through chamber **36** upon subsequent suctioning procedures." None of this is even hinted at by Iund.

All the elements of a cleaning chamber adjacent to the manifold having a funnel shape for creating a low pressure lift zone, a vortex cleaning action on the catheter, and a catheter wiper **38** located in the cleaning chamber are novel and unique to the present invention. Keeping all the above in mind and the limitations of both Kee and Iund, it is clearly apparent that any combination of Kee and Iund cannot possibly arrive at the uniqueness and usefulness of the present invention and should not be combined in the first place since there is no suggestion to do such.

It is also important to note that the present invention was not conceived of as merely an assembly of various well known elements, but rather an entirely new next generation suction system whose main purpose is to have all elements working synergistically with each other to produce a tracheal suction system which can stay connected to a patient's respiratory system for at least 72 hours if not longer. To accomplish this objective the system must have a totally closed hermetically sealed airtight suction control valve which includes a means for thoroughly and effectively cleaning the catheter prior to its being 100% sealed closed in an isolation chamber wherein the catheter is not left remaining in the ventilation manifold and catheter withdrawn secretions are not left to accumulate in the manifold without providing an effective means for removing those secretions from the manifold. **As such, it is very clear that the Examiner is incorrect in his**

assumptions that any combination of Kee or Iund can arrive at meeting the above objective.

The present inventor was clearly aware of both Kee and Iund and specifically drafted the Claims of the present invention to distinguish over all the prior art including Kee and Iund, and it is believed that the Claims as submitted are allowable. However, some changes to **Claims 1, 5, and 8** defined the specific type of open lumen to be a straight through, unobstructed open lumen portion. This language even more clearly distinguishes over Kee. Other Claims are resubmitted without amendment as their present language clearly distinguishes over Iund and Kee or any combination thereof.

Claims 45 and 46 are added. Claim 45 clearly distinguishes over the Kee and Iund patents in that it contains language defining a hermetically airtight sealed suction control valve and wherein the seal is opened solely by the catheter tip. Claim 46 also clearly distinguishes over both Kee and Iund in that it contains language defining a hermetically airtight sealed suction control valve and a catheter cleaning chamber configured to prevent rinse solution and secretions from entering the adjacent connector which clearly is not the case with Iund.

Favorable reconsideration of the original rejection and the allowance of all the Claims at bar is warranted and requested at this time. However, should the Examiner see language changes that he believes better define over the art relied

upon, such input in the furtherance of an allowance in the subject application is welcome.

The additional $84 fee for the addition of the two further independent Claims should be charged to the undersigned attorney's Deposit Account No. 04-1255.

Attached hereto is a marked-up version of the changes made to the Claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**." Also attached are the color highlighted drawings Referred to in the remarks and numbered as pages 20-23.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Amended) A suction system having a suction tube, a source of suction and a suction control valve, said suction control valve comprising: a housing having an upper surface and a first central linear passageway extending through said housing and in fluid flow communications at one end thereof with a suction tube and with a suction source at the other end thereof, said housing having a second passageway opening at said upper surface and transversing said first central linear passageway, a manually depressible and releasable plunger operable within said second passageway wherein said plunger includes a closed piston portion and an open, unobstructed, straight through lumen portion and is normally positioned within said first passage to a non-suction applied position where said piston portion is positioned across said first passageway to hermetically seal off fluid and air flow communication between said suction tube and said source of suction, said plunger further manually operable from said upper surface and depressible within said second passageway to a suction applied position where said open, unobstructed, straight through lumen portion is positioned in said first passageway and wherein there is unobstructed fluid and air flow communication between said suction tube and said source of suction, said plunger automatically returnable to its non-suction applied position upon manual release of said plunger.

3. (Amended) The suction control valve of claim 1 wherein the plunger includes [a wiper seal] outer surfaces adapted for sealing engagement with said second passageway.

5. (Amended) The suction system of claim 1 including a suction catheter and an actuator portion as part of the plunger, said first central linear passageway in fluid flow communication at one end with a suction catheter and at its other end with a suction source, said central passageway permitting unobstructed fluid and air flow between the suction catheter and the suction source, said plunger fitted within and hermetically sealed within the second passageway and the plunger depressably and releasably operable by the actuator within the second passageway wherein the plunger is normally positioned to a non-suction applied non-actuator depressed mode such that [the] said unobstructed, straight through fluid flow cross lumen is sealed by contact with the walls of the second passageway to prevent fluid and air flow communication between the suction tube and the suction source, said plunger further operable within the second passageway wherein the plunger is positioned to a suction applied actuator depressed mode such that [the] said unobstructed, straight through fluid flow cross lumen is unsealed and positioned within the first passageway to a fully open position to permit complete unobstructed fluid and air flow communication between the suction tube and the suction source.

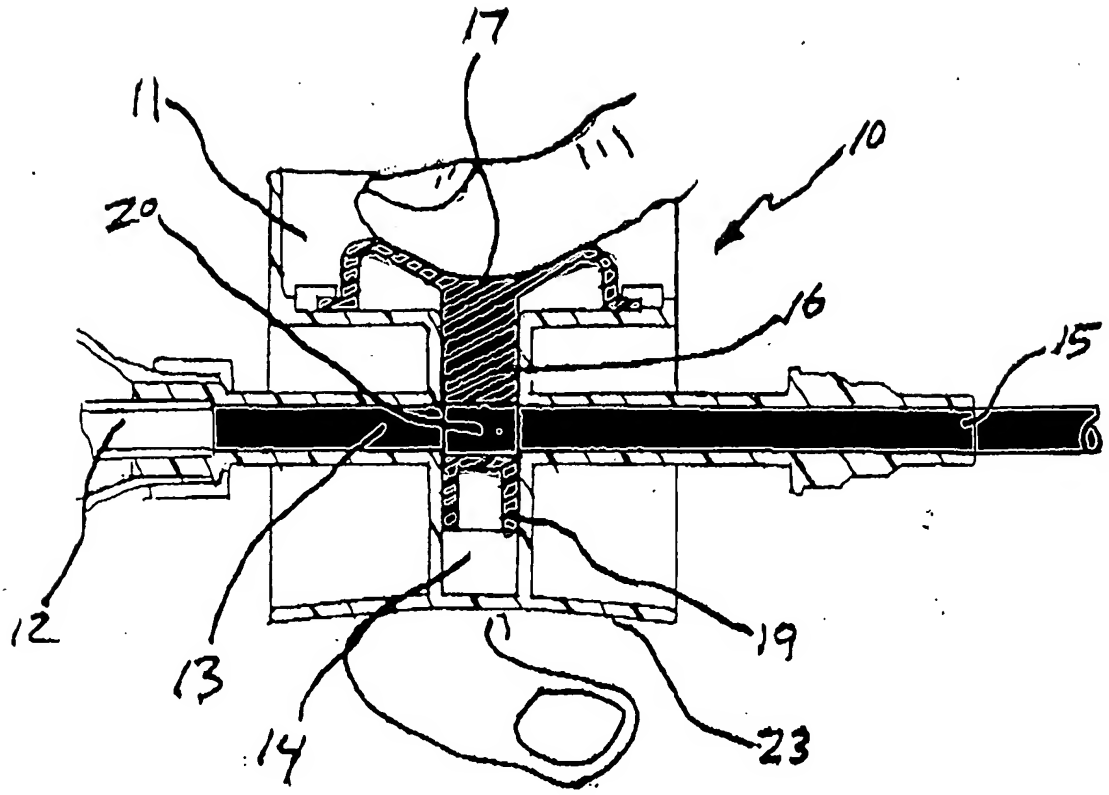
8. (Amended) A respiratory suction catheter system for suction secretions from a patient comprising: a frontal manifold configured for delivery of

ventilator air to a patient, a rearward suction control valve adapted for attachment to a source of suction, a suction catheter assembly including a suction catheter disposed between and operatively connecting the frontal manifold and the rearward suction control valve, said suction control valve in fluid and air flow communication at one end thereof with the suction catheter and at its other end with the source of suction, said suction control valve comprising: a housing having an upper surface and a first central linear passageway extending through said housing and in fluid flow communications at one end thereof with a suction tube and with a suction source at the other end thereof, said housing having a second passageway opening at said upper surfaces and transversing said first central linear passageway, a manually depressible and releasable plunger operable within said second passageway wherein said plunger includes a closed piston portion and an unobstructed, straight through open lumen portion and is normally positioned within said first passage to a non-suction applied position where said piston portion is positioned across said first passageway to hermetically seal off fluid and air flow communication between said suction tube and said source of suction, said plunger further manually operable from said upper surface and depressible within said second passageway to a suction applied position where said unobstructed, straight through open lumen portion is positioned in said first passageway and wherein there is unobstructed fluid and air flow communication between said suction tube and said source of suction, said

plunger automatically returnable to its non-suction applied position upon manual release of said plunger.

12. (Amended) A respiratory suction catheter system for suctioning secretions from a patient comprising: a connector having front and rear ends and configured for delivery of ventilator air to and from a patient, a cleaning chamber disposed adjacent to the rear end of said connector, the cleaning chamber having an entrance opening, a catheter wiper and a catheter isolator seal, the entrance opening disposed at the distal end of the cleaning chamber and the catheter isolator seal disposed at the proximal end of the cleaning chamber and the catheter wiper disposed between the entrance opening and the catheter isolator seal, a suction catheter assembly having a housing connected at its front end to said [closing] cleaning chamber and having a catheter in turn having a proximal end and a distal end, said catheter advanceable and retractable through the connector via said cleaning chamber.

FIG. 3



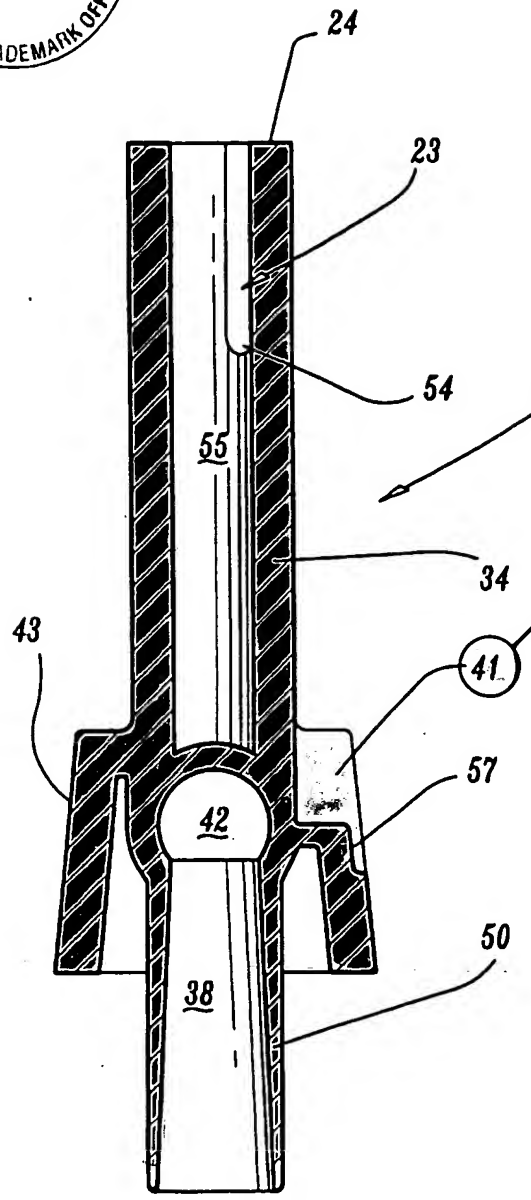


FIG. 7

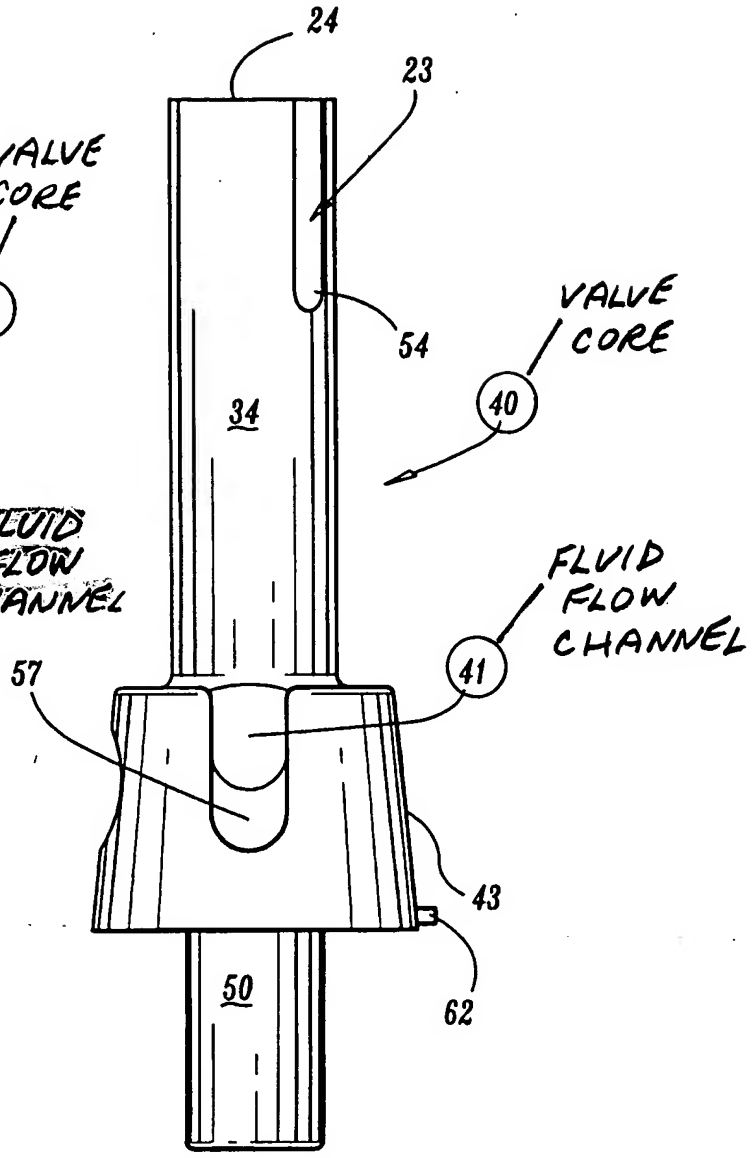


FIG. 8

Appl. No. 10/058,540

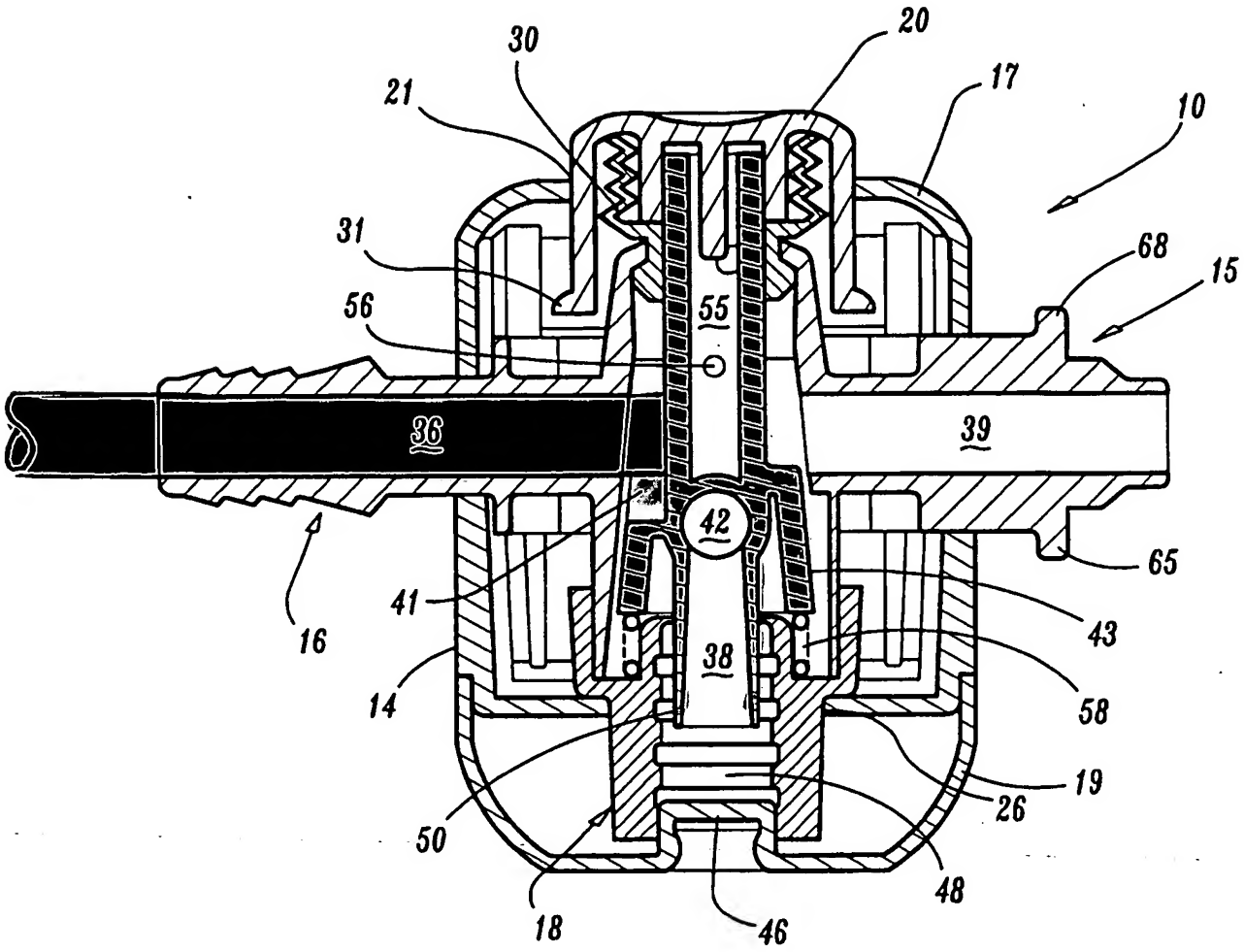


FIG. 11

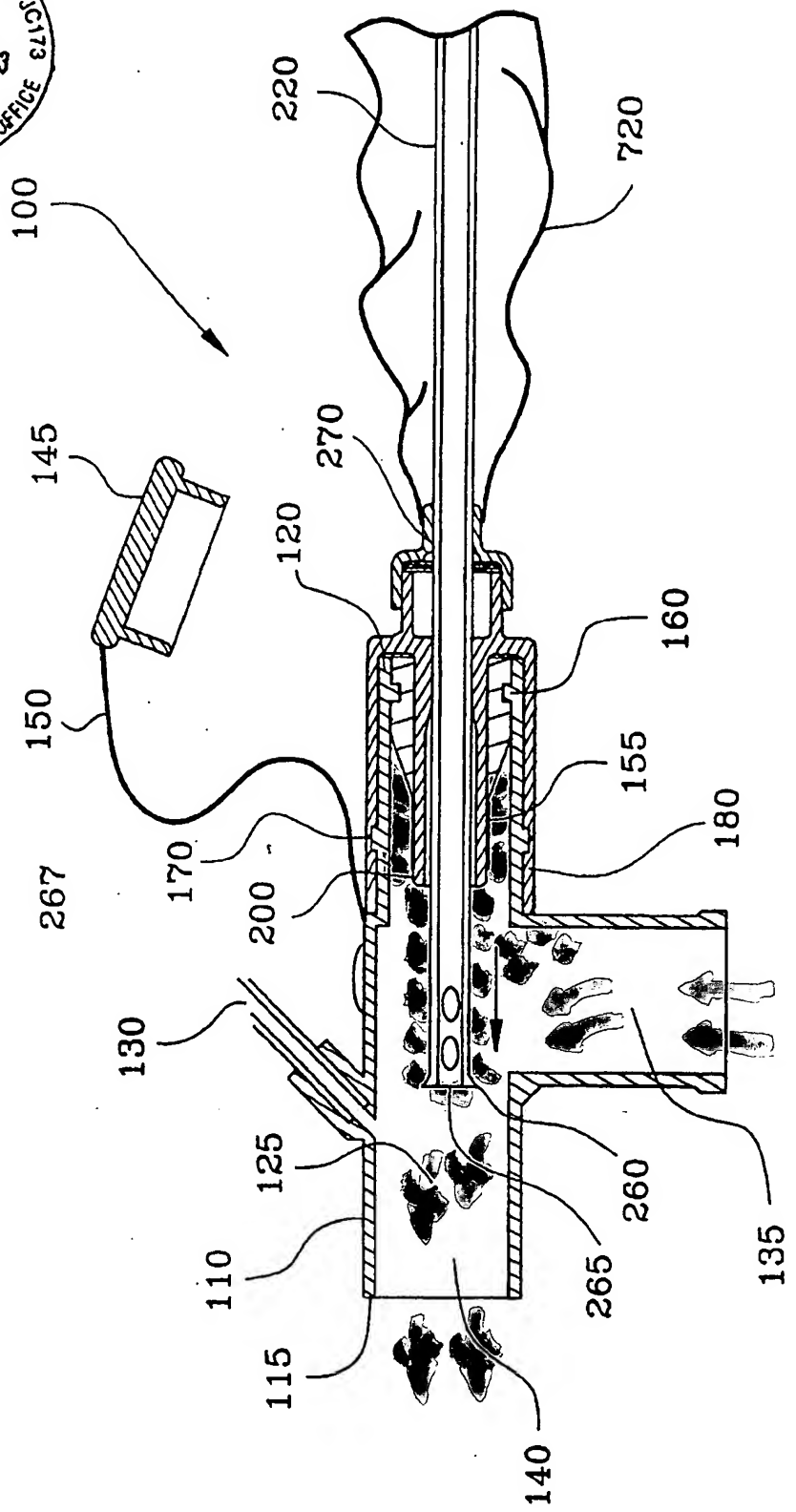


Fig. 4